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SECTION 5: 510(K) SUMMARY

JUN 0 6 2013

Device:	**AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, Adhesive and Non-Adhesive**
Applicant:	ConvaTec Inc.
Contact:	Katrina Fiedler Associate Director, US Regulatory Affairs Phone: 908-904-2541 Fax: 908-904-2235 Email: katrina.fiedler@convatec.com
Date:	**May 30, 2013**
Trade Name:	**AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, Adhesive and Non-Adhesive**
Classification Name:	Dressing, Wound, Drug
Device Class:	Unclassified
Product Code:	FRO
Predicate Devices:	AQUACEL™ Ag Hydrofiber™ Dressing, K080383, AQUACEL™ Foam Hydrofiber™ Foam Dressing (Adhesive and Non-Adhesive), Exempt, NAC Mepilex Border Ag Foam Dressing, K100029

Device Description

AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, Adhesive and Non-Adhesive is a soft, sterile foam wound dressing comprised of a waterproof outer polyurethane film and a multi-layered absorbent pad, with the adhesive dressing having a silicone adhesive border. The multi-layered absorbent pad contains a layer of polyurethane foam and a non-woven wound contact layer of silver Hydrofiber™ (sodium carboxymethylcellulose). The dressing's Hydrofiber™ wound contact layer contains 1.2% w/w ionic silver. The silver in the dressing kills a broad spectrum of wound bacteria held in the dressing. This dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement) without damaging healthy tissue. The outer film layer provides a waterproof viral and bacterial barrier which protects the wound from external contaminants.

The film also helps manage the moisture vapor transmission of the exudates absorbed by the dressing.

AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, Adhesive and Non-Adhesive may be used as a primary or secondary dressing. It may be used alone or in combination with other wound care products. The adhesive dressing has a silicone border which provides secure, skin friendly adhesion. This conformable and highly absorbent dressing absorbs wound fluids, creating a soft gel which maintains a moist environment. The moist wound environment is known to support the body's healing process.

Indications For Use

AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, Adhesive and Non-Adhesive is indicated for the management of wounds and can be used under the supervision of a healthcare professional. AQUACEL™ Ag Foam Hydrofiber™ Foam Dressings with Silver, Adhesive and Non-Adhesive may be used for the management of both chronic and acute wounds, such as partial thickness (second degree) burns; diabetic foot ulcers, leg ulcers(venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores(partial and full thickness), surgical wounds, traumatic wounds, wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites, abrasions, lacerations, minor cuts and minor scalds and burns.

The predicate AQUACEL Dressings in clinical studies shown to be successfully used in the management of chronic wounds. The subject device's technological characteristics are similar to the other AQUACEL predicate devices. The AQUACEL foam devices contain a polyurethane film which on the bench testing is shown to provide bacterial, viral and waterproof properties.

Thus we believe that, AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, Adhesive and Non-Adhesive is substantially equivalent to ConvaTec's previously cleared Hydrofiber™ technology based products (AQUACEL™ Ag Hydrofiber™ Dressing K080383 and AQUACEL™ Foam Hydrofiber™ Foam Dressing, NAC, Exempt) and Mölnlycke Health Care's Mepilex Border Ag Foam Dressing (K100029). In addition, we believe that AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, Adhesive and Non-Adhesive can be used safely and effectively for the management of wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 6, 2013

ConvaTec, Inc.
% Ms. Katrina Fiedler
Associate Director, US Regulatory Affairs
200 Headquarters Park Drive
Skillman, New Jersey 08558

Re: K123481
Trade/Device Name: AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, Adhesive and Non-Adhesive
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 22, 2013
Received: March 28, 2013

Dear Ms. Fiedler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21. CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123481

Device Name: AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, adhesive and non adhesive

Under the supervision of a healthcare professional:

AQUACEL™ Ag Foam Hydrofiber™ Foam Dressing with Silver, adhesive and non adhesive may be used for the management of both chronic and acute wounds, such as:

- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness);
- Surgical wounds
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and donor sites;
- Abrasions;
- Lacerations;
- Minor Cuts;
- Minor scalds and burns.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ _

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123481